

## EXPRESS MAIL CERTIFICATE

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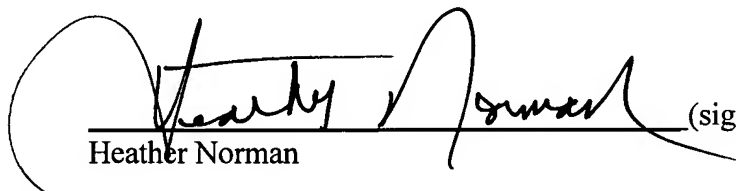
Date of Deposit : May 17, 2004

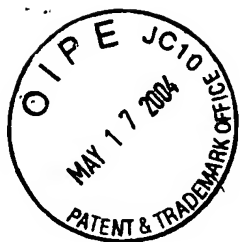
Type of Documents : Information Disclosure Statement;  
Form 1449;  
Cited References / twenty-three (23); and  
Return Postcard

Serial No. : 10/670,896

Filing Date : September 25, 2003

I hereby certify that the documents identified above are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

 (signature)  
Heather Norman



05-18-04

IFW

**PATENTS**  
EV 336 697 808 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re:	Hotta, <i>et al.</i>	:	Examiner:	To be assigned
Serial No.:	10/670,896	:	Art Unit:	3762
Filed:	September 25, 2003	:	Docket No.:	B185 1180.1 (MSC 8011)

For: **Methods for Removal of Contaminants from Blood Product Solutions**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby voluntarily disclose the references listed on the attached Form PTO-1449 to the Commissioner for Patents. Copies of twenty-three (23) references listed on Applicants' form PTO-1449 are enclosed herewith. This Information Disclosure Statement is being submitted prior to the mailing of a first Office Action on the merits of the application. Accordingly, no fees are due. However, should any fee be due in connection with this submission, the Commissioner is hereby authorized to charge those fees to Deposit Account No. 09-0528.

The reference D4 (Burnouf-Radosevich, M., "Viral Safety of Intravenous Immunglobulins G for Therapeutic Use," *Transfus. Clin. Biol.*, 2(3): 167-179 (1995)) is a French language document that appears to discuss at least some aspect of nanofiltration for the specific removal of viruses based on size (document was published with an English language abstract).

Also, Applicants are not aware of the date the information in reference D14 (Planova® Filters, Planova® Filters for Virus Removal, Asahi Kasei Corporation, Planova® Division, [www.asahi-kasei.co.jp/planova/product/filters.html](http://www.asahi-kasei.co.jp/planova/product/filters.html), pp. 1-4.) was made available to the public.

The enclosed copies of documents D16 – D20 are complete. Each original document contained numbered divider pages which do not appear in the enclosed copies; consequently, there are no missing pages in the enclosed copies.


This statement should not be construed as the representation that any search has been made, or that the information cited herewith is material, or that there does not exist information more material to the examination of the present Application. The Examiner is specifically requested not to rely solely on the information submitted herein. On the contrary, the Examiner is requested to conduct an independent and thorough review of all available information, and to form independent opinions as to its significance.

Applicants further reserve the right to establish the patentability of the claimed invention over any of the listed information should they be applied as references, and/or to prove that the cited information may not be prior art, and/or to prove that the cited information may not be enabling for the teachings they purport to offer.

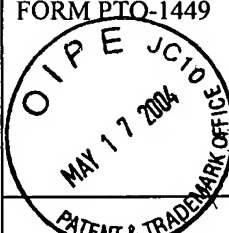
The Examiner is respectfully requested to initial and return copies of the enclosed Form PTO-1449 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

Respectfully submitted,

Date: May 17, 2004

  
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Registration No. 44,224  
Attorney for Applicants

Docket: **B185 1180.1 (MSC 8011)**  
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FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DKT NO. B185 1180.1		SERIAL NO. 10/670,896	
		INFORMATION DISCLOSURE STATEMENT BY APPLICANT					
		APPLICANT Hotta, <i>et al.</i>				FILING DATE 09/25/03	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CL.	SUBCL.	FILING DATE IF APPROP.
	P1	US 2002/0192794 A1	12/19/02	Dadd, <i>et al.</i>	435	217	
	P2	US 2002/0009707 A1	01/24/02	Nur, <i>et al.</i>	435	2	
	P3	6,096,872 A	08/01/00	Van Holten, <i>et al.</i>	530	390.1	
	P4	5,886,154	03/23/99	Lebing, <i>et al.</i>	530	390.1	
	P5	2,390,074	12/04/45	Cohn, <i>et al.</i>	260	122	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NO.	DATE	COUNTRY	CL.	SUBCL.	TRANSLATION
	F1	EP 1 206 961 A1	05/22/02	EP			
	F2	WO 01/36611 A1	05/25/01	WO			
	F3	WO 98/37086	08/27/98	WO			
<b>OTHER DOCUMENTS (Incl. Author, Title, Date, Pertinent pages, etc.)</b>							
	D1	Abe, H., <i>et al.</i> , "Removal of Parvovirus B19 from Hemoglobin Solution by Nanofiltration," <i>Art. Cells, Blood Subs., and Immob. Biotech.</i> , 28(5): 375-383 (2000).					
	D2	Aranha, H., "Viral Clearance Strategies for Biopharmaceutical Safety Part 2: Filtration for Viral Clearance," Reprinted from <i>Biopharm.</i> , 8 pages (2001).					
	D3	Burnouf-Radosevich, M., <i>et al.</i> , "Nanofiltration, a New Specific Virus Elimination Method Applied to High-Purity Factor IX and Factor XI Concentrates," <i>Vox. Sang.</i> , 67(1): 132-138 (1994).					
	D4	Burnouf-Radosevich, M., "Viral Safety of Intravenous Immunglobulins G for Therapeutic Use," <i>Transfus. Clin. Biol.</i> , 2(3): 167-179 (1995).					
	D5	Carter, J., and H. Lutz, "An overview of viral filtration in biopharmaceutical manufacturing," <i>European Journal of Parenteral Sciences</i> , 7(3): 72-78 (2002).					
	D6	Hotta, J., <i>et al.</i> , "Significant Parvovirus Removal and Product Recovery from an IgG-containing Solution using Planova Filters," PDA/FDA Viral Clearance Forum, 1 page (October 2001).					
	D7	Ide, S., "Development of New Planova® Membrane – the Planova® 20N Filter," Planova® Workshop Tokyo, Japan, pp. 135-145 (November 1, 2000).					
	D8	Korneyeva, M., "Factors Influencing Virus Removal and Product Yield During Nanofiltration of Highly Purified Plasma-Derived Protein with Thrombolytic Activity," <i>Slides from Oral Presentation</i> , 29 <sup>th</sup> World Congress of the International Society of Hematology, Seoul, Korea, pp. 1-17 (August 24-28, 2002).					
	D9	Li, H., <i>et al.</i> , "Low pH of Feed Solutions Significantly Increases Procine Parvovirus Aggregate Formation," <i>Slides from Oral Presentation</i> , PDA/FDA Viral Clearance Forum, Washington, DC, pp. 1-18 (October 1-3, 2001).					
	D10	McNaull, S., <i>et al.</i> , "Parvovirus Removal from an IgG-containing Solution at Extended Challenge Volume Using an Ultrafiltration Membrane in Normal-Flow Configuration," <i>Slides from Oral Presentation</i> , PDA/FDA Viral Clearance Forum, Washington, DC, pp. 1-12 (October 1-3, 2001).					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO -1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DKT NO. B185 1180.1	SERIAL NO. 10/670,896
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use several sheets if necessary)</i>				APPLICANT Hotta, <i>et al.</i>	
				FILING DATE 09/25/03	GROUP 3762
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, etc.)</i>					
	D11	O'Grady, J., <i>et al.</i> , "Virus Removal Studies Using Nanofiltration Membranes," Viral Safety and Evaluation of Viral Clearance from Biopharmaceutical Products, <i>Dev. Biol. Stand.</i> , 88: 319-326 (1996).			
	D12	Omar, A., and C. Kempf, "Removal of Neutralized Model Parvoviruses and Enteroviruses in Human IgG Solutions by Nanofiltration, <i>Transfusion</i> , 42: 1005-1010 (2002).			
	D13	Troccoli, N.M., <i>et al.</i> , "Removal of Viruses from Human Intravenous Immune Globulin by 35 nm Nanofiltration," <i>Biologicals</i> , 26: 321-329 (1998).			
	D14	Planova® Filters, Planova® Filters for Virus Removal, Asahi Kasei Corporation, Planova® Division, 4 pages, <a href="http://www.asahi-kasei.co.jp/planova/product/filters.html">www.asahi-kasei.co.jp/planova/product/filters.html</a> (date of public availability unknown).			
	D15	Section 3.1. <u>Virus validation studies for Parvovirus B19</u> , Plasma Protein Therapeutics Association Europe, pp. 5-9 (February 14, 2000).			
	D16	Planova® Workshop 2002, Biotherapeutic Production, Safety, and Validation with Planova® Filtration Products, Bethesda, Maryland, USA, Asahi Kasei Corporation, entire publication, (October 10, 2002).			
	D17	Planova® Workshop 2001, Virus removal filtration: applications, advances, and analyses, Montecatini Terme, Italy, Asahi Kasei Corporation, entire publication, (September 24 - 25, 2001).			
	D18	Planova® Workshop Japan, A forum for exchanging information on the latest developments in virus removal filtration, Tokyo, Japan, Asahi Kasei Corporation, entire publication, (November 1, 2000).			
	D19	Planova® Workshop USA '99, A forum for exchanging information on the latest developments in virus removal technology, Washington, DC, USA, Asahi Chemical Industry Co., Ltd., entire publication, (November 29, 1999).			
	D20	Planova™ Workshop, To meet and exchange information on the latest developments in virus removal technology, Oslo, Norway, Asahi Chemical Industry Co., Ltd., entire publication, (June 27, 1998).			
EXAMINER			DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					